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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/518,076	03/03/2000	Leland Shapiro	SHAP-000200	5437

68514 7590 11/26/2007  
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EXAMINER
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HILL, MYRON G

ART UNIT	PAPER NUMBER
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1648

MAIL DATE	DELIVERY MODE
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11/26/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

09/518,076

Applicant(s)

SHAPIRO, LELAND

Examiner

Myron G. Hill

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 13 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-14, 16, 21, 28, 31 and 38-40 is/are pending in the application.
- 4a) Of the above claim(s) 10, 11, 16, 21, 28, 31 and 38-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, and 12-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This action is in response to the response and petition filed 3/13/07 and follows the petition decision of 9/18/07 at which time the application was forwarded to the examiner.

Applicant has cancelled claims to the elected species and now amends claim 1 to read on a method using a substance having AAT activity and a nucleotide wherein the substance is now a peptide. The examiner now will examine the new genus of peptides and will choose the first species to examine, in this case AAT will be the first examined member of the genus. This reads on claims 1-8, and 12-14, newly submitted claim 40 is drawn to non-elected peptide and is withdrawn from consideration

Claims 1-8, and 12-14 are under consideration.

Claims 10, 11, 16, 21, 28, 31, 38-40 are withdrawn.

### ***Rejection Withdrawn***

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1, 3, and 4 were rejected under 35 U.S.C. 103(a) as being unpatentable over Lezdey (US 5,532,215, previously cited) in view of Gyorkos *et al.* (US 5,618,852, previously cited) and Guittard *et al.* (US 5358721).

Applicant has canceled and amended claims. The rejection is withdrawn because a modified rejection would be duplicative of the maintained rejection

### ***Rejections Necessitated By Amendment***

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 14 recites the limitation "substance" in line 1. There is insufficient antecedent basis for this limitation in the claim.

### ***Rejections Maintained***

#### ***Claim Rejections - 35 USC § 103***

Claims 1- 8, 12- 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lezdey (US 5,532,215, previously cited) and Guittard *et al.* (US 5358721).

Applicant argues that the claims are not obvious, there is no motivation to combine, that Guittart et al. appears to be directed to gastrointestinal delivery, and that peptides are degraded in the gastrointestinal tract.

Applicant's arguments have been fully considered and not found persuasive.

As previously stated, it would have been obvious to combine two methods useful in treating the same condition and one of ordinary skill in the art would have had an expectation of at least additive effect. Applicant has provided no argument that the results are unexpected.

Applicant's argument that AAT is degraded in the gastrointestinal tract is not persuasive. First, applicant's cited reference is general and does not show that the AAT of Lezdey would be degraded in the gastrointestinal tract. Second, the claims are not limited to the gastrointestinal tract, nor does as the method require that both components be administered at the same time and administered to the same site. Also, the claims include AAT which is taught in the prior art. Claims 6 and 7 add product by process limitations that simply indicate from where it is purified.

Thus the rejection is maintained.

### ***Conclusion***

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 8:30 am-5 pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Myron G. Hill  
Patent Examiner  
14 November 2007

/Bruce Campell/  
Supervisory Patent Examiner  
Art Unit 1648